HFD-613

NDA 17-735/S-084
NDA 17-919/S-066

JAN 06 1999

The R.W. Johnson Pharmaceutical Research Institute
Attention: Ms. Donna Panasewicz
Manager, Regulatory Affairs
920 Route 202 South
P.O. Box 300
Raritan, NJ 08869-0602

Dear Ms. Panasewicz:

Please refer to your supplemental new drug applications dated October 16, 1997, received October 17, 1997, submitted under section 505(b) of the FederalFood, Drug, and Cosmetic Act for:

Modicon -28 (norethindrone and ethinyl estradiol) Tablets (NDA 17-735); and
Ortho-Novum -28 (norethindrone and ethinyl estradiol) Tablets (NDA 17-919).

We note that these supplements were submitted as 'Special Supplement - Changes Being Effected' under 21 CFR 314.70(c).

These supplemental new drug applications provide for a revision in the Patient Brief Summary, subsection 2. such that it now reads:

"In rare cases, oral contraceptives can cause benign but dangerous liver tumors.These benign liver tumors can rupture and cause fatal internal bleeding.In addition, some studies report an increased risk of developing liver cancer.However, liver cancers are rare. "

Your submission stated that these changes have been implemented.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are Safe and effective for use as recommended in the submitted final printed labeling (patient package insert submitted October 16, 1997). Accordingly, these supplemental applications are approved.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Christina Kish, Project Manager, at (301) 827-4260.

Sincerely,

1/5/95

Lisa D. Rarick, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation-and Research